

Claims

1. The use of a combined composition comprising hydrocortisone and a delivery vehicle wherein said delivery vehicle provides for delayed and sustained release of hydrocortisone, for the manufacture of a medicament for use in the treatment of depression, or a condition which results in depression, or similar condition..
2. Use according to Claim 1 wherein said disease or condition is selected from the group consisting of: depression, sleep disorder, fatigue, abnormal eating, addiction, anxiety, jet lag chronic fatigue syndrome; myalgic encephalitis; jet lag; shift work, depression resulting from a person being overweight; depression resulting from dieting; depression resulting from the treatment of cigarette addiction; depression resulting from the treatment of alcohol addiction; depression resulting from the treatment of drug addiction; the treatment of seasonal affective disorder or a like condition.
3. Use according to Claim 2 wherein said disease or condition is depression, or similar condition.
4. Use according to Claim 3 wherein the depression is clinical depression.
5. Use according to Claim 3 wherein the depression is reactive depression.
6. Use according to Claim 3 wherein the depression is post-natal depression.
7. Use according to Claim 1 wherein the condition results from the administration of an antipsychotic drug.
8. Use according to Claim 7 wherein the antipsychotic drug is selected from the group consisting of: clozapine, olanzapine, risperidone, quetiapine or sertindole.

9. A method for the treatment of diseases or conditions that result in depression, or a condition which results in depression, or similar condition, comprising the steps of:

- 5 i) providing a combined preparation of hydrocortisone, or a functional variant thereof, and a delivery vehicle wherein said vehicle provides for the sustained release of hydrocortisone or variant thereof;
- ii) administering the combined preparation in (i) to an animal requiring treatment such that hydrocortisone, or variant thereof, is released in a
10 sustained manner;
- iii) providing a combined preparation of hydrocortisone, or variant thereof, and a delivery vehicle wherein said vehicle provides for the delayed but sustained release of hydrocortisone, or variant thereof;
 and
- 15 iv) administering the combined preparation in (iii) to an animal requiring treatment such that hydrocortisone, or variant thereof, is released in a delayed but sustained manner.

20 10. A method according to Claim 9 wherein said disease or condition is depression.

25 11. A method according to Claim 9 or 10 wherein said animal is administered hydrocortisone which is released in a sustained manner which is followed by hydrocortisone which is released in a delayed but sustained manner.

 12. A method according to any of Claims 9-11 wherein said animal is human.

30 13. A method according to any of Claims 9-12 wherein said variant is cortisol or cortisone.

14. A method according to any of Claims 9-13 wherein said condition is selected from the group consisting of: chronic fatigue syndrome; myalgic encephalitis; jet lag; shift work; depression resulting from a person being overweight; depression resulting from a person dieting; depression resulting from the treatment of addiction, for example smoking or drugs; alcohol addiction; the treatment of seasonal affective disorder or a like condition.

15. A method according to Claim 9 wherein said condition results from the administration of an antipsychotic drug.

16. A method according to Claim 15 wherein said drug is selected from the group consisting of: clozapine, olanzapine, risperidone, quetiapine or sertindole.

17. A method according to any of Claims 9-16 wherein said sustained release preparation is administered in the morning, preferably between 08:00 and 12:00.

18. A method according to any of Claims 9-16 wherein said delayed and sustained release formulation is administered in the evening, preferably between 18:00 and 24:00.

19. The use of a combined composition comprising a glucocorticoid, and a delivery vehicle wherein said delivery vehicle provides for delayed and sustained release said glucocorticoid for the manufacture of a medicament for use in the treatment of side effects due to the administration of said glucocorticoid.

20. Use according to Claim 19 wherein said glucocorticoid is selected from the group consisting of: hydrocortisone or a functional variant thereof; cortisol; cortisone acetate; prednisolone; prednisone; dexamethasone

21. Use according to Claim 19 or 20 wherein said side effect is increasing weight gain.
22. Use according to Claim 19 or 20 wherein said side effect is reduction in bone density.
23. Use according to Claim 19 or 20 wherein said side effect is muscle or skin wastage.
24. Use according to Claim 19 or 20 wherein said side effect is insulin resistance.
25. A method for the treatment of an animal which animal is suffering from side effects as a result of glucocorticoid administration, comprising the steps of:
- i) providing a combined preparation of a glucocorticoid and a delivery vehicle wherein said vehicle provides for the sustained release of said glucocorticoid;
 - ii) administering the combined preparation in (i) to an animal requiring treatment such that the glucocorticoid is released in a sustained manner;
 - iii) providing a combined preparation of a glucocorticoid and a delivery vehicle wherein said vehicle provides for the delayed but sustained release of said glucocorticoid; and
 - iii) administering the combined preparation in (iii) to an animal requiring treatment such that the glucocorticoid is released in a delayed but sustained manner.
26. A method according to Claim 25 wherein said glucocorticoid is selected from the group consisting of: hydrocortisone or a functional variant thereof; cortisol; cortisone acetate; prednisolone; prednisone; dexamethasone.

27. A method according to Claim 25 or 26 wherein said side effect is increasing weight gain.

5 28. A method according to Claim 25 or 26 wherein said side effect is reduction in bone density.

29. A method according to Claim 25 or 26 wherein said side effect is muscle or skin wastage.

10 30. A method according to Claim 25 or 26 wherein said side effect is insulin resistance.

31. The use of a combined composition comprising hydrocortisone and a delivery vehicle wherein said delivery vehicle provides for delayed and sustained release of hydrocortisone, for the manufacture of a medicament to restore and entrain the endogenous circadian rhythm of cortisol in conditions that do not result from cortisol deficiency but are a consequence of a disruption in the normal circadian secretion of cortisol.

20

25

30